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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,456	04/07/2004	Mark L. Nelson	PKZ-058CN	7274
959	7590	09/30/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP.			BADIO, BARBARA P	
28 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	

1616

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/820,456

Applicant(s)

NELSON ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## First Office Action on the Merits

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 8 of U.S. Patent No. 6,617,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass 7-N-substituted phenyl tetracycline compounds. The claims of the cited patent differ from these of the instant application by the recitation of a broader genus of 7-substituted tetracycline compounds, i.e., the claims of the cited patent encompass all 7-substituted tetracycline compounds wherein said substituent is a substituted or unsubstituted phenyl group. However, the instantly claimed compounds are anticipated by the cited patent based on the disclosure of 7-N-substituted phenyl tetracycline such as 7-(4-nitrophenyl)sancycline (see for example, claim 4).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7, 9, 10, 12, 13, 16, 18, 23-25 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claim 7 is drawn to the claimed compounds having a 2-amino substituent phenyl group in the 7-position but is dependent on claim 5 that recites 7-(2-nitrophenyl)sancycline;

Claim 10 recites "7-(4-N,N-dimethylaminophenyl)sancycline" but is dependent on claim 9 that is drawn to a 2-N-substituted phenyl derivative;

Claim 12 recites a 3-N-substituted phenyl derivative but is dependent on claim 10 that recites a 4-N-substituted phenyl derivative;

Claim 16 recites "[t]he method of claim 14", however, claim 14 is a compound claim;

Claim 18 recites "7-(4-N,N-dimethylaminophenyl)sancycline" but is dependent on claim 17 that is drawn to a 3-N-substituted phenyl derivative;

Claim 23 recites "wherein said 4-amino substituent is dialkyl". Is the 4-amino substituent "dialkyl" or "dialkylamino". For the purpose of art rejection, it is assumed applicant intended the latter;

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Claim 24 recites "7-(4-aminophenyl)sancycline" but is dependent on claim 23 that recites 4-dialkylamino derivatives;

Claim 25 recites "wherein said dialkyl amino group is dimethyl". Does applicant intend "dimethyl" or "dimethylamino". For the purpose of art rejection, it is assumed applicant intended the latter; and

Claim 40 is dependent on claim 39 drawn to 4-amino phenyl substituted derivatives but recites "7-(4-nitrophenyl)sancycline".

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 2, 10, 18-23, 25, 26, 47 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Koza.

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Koza teaches 7-substituted tetracycline derivatives such as 7-(4-nitrophenyl)sancycline and 7-(4-dimethylphenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 5 and 6). The compounds taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koza.

Koza teaches 7-substituted tetracycline derivatives such as 7-(4-nitrophenyl)sancycline and 7-(4-dimethylphenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 5 and 6).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. For example, claims 3-9 and 11-17 recite the claimed compounds having a 2- or 3-substituted phenyl substituent attached to the 7-position.

These compounds are positional isomers of the prior art compounds and, thus, are unpatentable unless they possess some unobvious or unexpected beneficial property not possessed by the prior art compounds. In re Norris, 179 F.2d 970, 84

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USPQ 458 (CCPA 1970). The motivation to make positional isomers of the prior art compounds is based on the close structural similarity of the compounds and the expectation in the art that positional isomers would have similar properties.

Claims 27-46 differ from the reference by reciting treatment of a tetracycline responsive state such as bacterial infection. However, tetracycline and its derivatives are known broad-spectrum antibiotics useful against a vast number of bacterial infections (see Koza page 815, 1<sup>st</sup> paragraph). Thus, the use of any tetracycline derivative, including those taught by Koza and recited by the instant claims, in treating bacterial infections would be prima facie obvious. The motivation to use these compounds as recited by the instant invention would be based on the knowledge of the skilled artisan in the art and, thus, the expectation that any tetracycline derivative would be useful in treating tetracycline responsive disease states including bacterial infections.

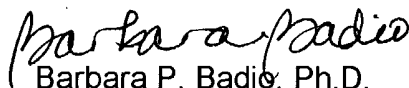
### ***Telephone Inquiry***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
September 28, 2004